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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,503	03/02/2006	Patrick Stordeur	DECLE35.005APC	6280

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
WHISENANT, ETHAN C	

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
01/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,503	STORDEUR ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-13,15-22,24-33,35-47,49-55 and 57-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,12,15,16,18,22,24,31-33,35-46,52 and 61* is/are rejected.

7)☒ Claim(s) *13,17,19-21,25-30,47,51,53-55 and 57-60* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

NON-FINAL ACTION

1. The applicant's response (filed 11 NOV 08) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 1-9, 11-13, 15-22, 24-33, 35-47, 49-55 and 57-61** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> or
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

CLAIM REJECTIONS UNDER 35 USC § 102

3. **Claim(s) 1-5, 11-12, 15-16, 18, 22, 24, 31** is/are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. [US 2004/0161788 (2004)].

Claim 1 is drawn to a vessel suitable for accepting a liquid biological sample.

Chen et al. teach a vessel suitable for accepting a liquid biological sample which comprises all of the limitations recited in Claims 1-5. See, at least, for example, Examples 1-13 on pages 9-16.

Claim 11 is drawn to an embodiment of the vessel of Claim 1 wherein the vessel further comprises a valve which is capable of minimizing the flow of gas/liquid from the vessel and allowing the flow of liquid biological sample into the vessel.

Chen et al. teach this limitation. See element 310 in Fig. 1B and the description thereof in paragraph [0074].

Claim 12 is drawn to an embodiment of the vessel of Claim 1 wherein the vessel further comprises a means through which displaced gas may be expelled.

Chen et al. teach this limitation. See element 26 in Fig. 1B which according to paragraph [0036] is a vent hole.

Claim 15 is drawn to an embodiment of the vessel of Claim 1 wherein said force transmits an opening means to said physical barrier.

Chen et al. teach this limitation. See at least for example paragraph [0074].

Claim 16 is drawn to an embodiment of the vessel of Claim 1 wherein said force irreversibly opens said physical barrier.

Chen et al. inherently teaches this limitation. See at least, for example, paragraph [0074].

Claim 18 is drawn to an embodiment of the vessel of Claim 1 wherein said first substance comprises one or more immune system antigens.

Chen et al. inherently teaches this limitation. Note that the proteinase K found in for example subsection 122 is absent as showing to the contrary a immune system antigen. See at least, for example, paragraph [0072].

Claim 22 is drawn to an embodiment of the vessel of Claim 1 wherein said stabilizing agent is an inhibitor of cellular RNA degradation and/or gene induction..

Chen et al. inherently teaches this limitation. Note that the proteinase K (i.e. the stabilizing agent in at least one embodiment of Chen et al.] found in for example subsection 122 is, absent as showing to the contrary, an inhibitor of cellular RNA degradation and/or gene induction. See at least, for example, paragraph [0072].

Claim 24 is drawn to a method of testing RNA components in a stabilized blood sample which comprises pulsing a sample of blood with an antigen in the vessel according to Claim 1, inhibiting cellular RNA degradation and/or gene induction therein, testing the RNA components in the blood so-inhibited, thereby testing RNA components in a stabilized blood sample.

Chen et al. teach this embodiment. Note especially Examples 4, 6 and 8 on pp.11 -13.

Claim 31 is drawn to a method of testing RNA components in a stabilized blood sample.

Chen et al. teach this embodiment. Note especially Examples 4, 6 and 8 on pp.11-13.

35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim Rejections under 35 USC § 103

6. **Claim(s) 6-9, 32** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. [US 2004/0161788 (2004)].in view of Lee et al. [US 2002/0064484 (2002)].

Claim 6 is drawn to an embodiment of the vessel of Claim 1 wherein the vessel comprises one or more areas suitable for puncture by a syringe needle.

Chen et al. teach a vessel suitable for accepting a liquid biological sample which comprises all of the limitations of Claim 6 except Chen et al. fail to teach that their vessel comprises one or more areas suitable for puncture by a syringe needle. Chen et al. do teach that the opening at the top of the tube may be covered by a cap. Furthermore, Lin et al. teach a cap which comprises a re-sealable septum suitable for puncture by a syringe needle (i.e. a fitting suitable for receiving a syringe needle and transmitting the contents therein to the interior of said vessel). Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the vessel of Chen et al. wherein a cap as described by Lin et al. is used in place of the cap of Chen et al. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary

artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Claim 32 is drawn to a method of testing RNA components in a stabilized blood sample.

Chen et al. in view of Lin et al. reasonably suggest this embodiment. Note especially Examples 4, 6 and 8 on pp.11-13 of Chen et al.

7. Claim(s) 33, 35-39, 45-46, 49-50, 52, 61 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. [US 2004/0161788 (2004)].in view of the Stratagene Catalog (1988).

Claim 33 is drawn to kit suitable for pulsing a liquid biological sample with a first agent and subsequently introducing an agent that inhibits cellular RNA degradation and /or gene induction thereto and testing mRNA components in the stabilized blood sample so pulsed.

Chen et al. teach a vessel which meets all of the structural limitations of the vessel recited in Claim 33. Chen et al. do not teach packaging their vessel(s) in a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. In addition the Stratagene catalog teaches the advantages of assembling a kit, such as, saving resources and reducing waste. Therefore, absent an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the teachings of Chen et al. with the teachings of the Stratagene Catalog wherein the vessels necessary to perform the method Chen et al. are placed into a kit

format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

8. **Claim(s) 40-43** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. [US 2004/0161788 (2004)].in view of the Stratagene Catalog (1988) as applied against 33 above and further in view of Lee et al. [US 2002/0064484 (2002)].

Claim 40 is drawn to an embodiment of the kit of Claim 33 wherein the vessel comprises one or more areas suitable for puncture by a syringe needle.

Chen et al. in view of the Stratagene Catalog reasonably suggest a kit comprising vessel suitable for accepting a liquid biological sample which comprises all of the limitations of Claims 40-43 except Chen et al. in view of the Statagene Catalog fail to teach that their vessel are to comprise one or more areas suitable for puncture by a syringe needle. Chen et al. do teach that the opening at the top of the tube may be covered by a cap. Furthermore, Lin et al. teach a cap which comprises a re-sealable septum suitable for puncture by a syringe needle (i.e. a fitting suitable for receiving a syringe needle and transmitting the contents therein to the interior of said vessel). Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the kit /vessel of Chen et al. in view of the Statagene Catalog wherein a cap as described by Lin et al. is used in place of the cap of Chen et al. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their

common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

9. **Claim(s) 44** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. [US 2004/0161788 (2004)].in view of the Stratagene Catalog (1988) as applied against 33 above and further in view of Lee et al. [US 2002/0064484 (2002)] and Swenson [US 2003 /0181868(2003)].

Claim 44 is drawn to an embodiment of the kit of Claim 33 wherein the vessel comprises one or more cannulas suitable for withdrawing bodily fluids.

Chen et al. in view of The Stratagene Catalog reasonably suggest a kit which comprises all of the limitations of Claim 44 except Chen et al. in view of The Stratagene Catalog fail to teach that their vessel(s) are to comprises one or more cannulas suitable for withdrawing bodily fluids. Chen et al. do teach that the opening at the top of the tube may be covered by a cap. Furthermore, Lin et al. teach a cap which comprises a re-sealable septum suitable for puncture by a syringe needle (i.e. a fitting suitable for receiving a syringe needle and transmitting the contents therein to the interior of said vessel). In addition Swenson teach a needle cannula device suitable for withdrawing bodily fluids (e.g. blood). Finally, Swenson teach that their needle cannula device provides some degree of protection from needle sticks for the technician tasked with drawing the blood from a patient. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the vessel of Chen et al. wherein a cap as described by Lin et al. is used in place of the cap of Chen et al. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Furthermore, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the kit reasonably suggested by the combination of Chen et al. view of the Stratagene Catalog and Lee et al. wherein the vessel(s) are modified such that they comprise a needle cannula suitable for withdrawing bodily fluids. The ordinary artisan would have been motivated to make the modification recited above in order to provide the technician tasked with obtaining blood in order to perform the assay(s) of Chen et al. with protection against accidental needle sticks.

CLAIM OBJECTIONS

10. Claim(s) 13, 17, 19-21, 25-30, 47, 51, 53-55 and 57-60 is /are objected to as being dependent upon a rejected base claim, but would appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

11. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection.

CONCLUSION

12. Claim(s) 1-9, 11-13, 15-22, 24-33, 35-47, 49-55 and 57-61 is/are rejected and/or objected to for the reason(s) set forth above.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-

Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/
Primary Examiner
Art Unit 1634